K080514

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 2 6 2008

Submitter

Company:.....3M ESPE AG

Street:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State: .....Bavaria

Country: .....Germany

Establishment Registration Number 9611385

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Date:.....February 18, 2008

Name of Devices

Proprietary Name:.....PECD-01

.....PECD Quick-01

Classification Name:.....Impression material

Common Name: .....Dental impression material

Predicate Devices

Impregum™ Penta™ M Monosoft by 3M ESPE.....K994192

Poly Q Penta M by 3M ESPE.....K032001

Ramitec Penta by 3M ESPE K952693

Description for the Premarket Notification

PECD-01 and PECD Quick-01 are classified as Impression material (21 C.F.R. § 872.3660) because the products are devices intended to reproduce the structure of a patient's teeth.

3M ESPE is submitting this 510(k) premarket notification for modifications to its polyether based impression material Impregum Penta M Monosoft. The modification is in chemical composition but, however, the fundamental character of the chemistry of Impregum Penta M Monosoft was not changed. Like Impregum Penta M Monosoft, PECD-01 and PECD Quick-01 are polyether tray impression materials of medium-bodied consistency. While Impregum Penta M Monosoft is intended to be used in 3M ESPE's automatic mixing, dosing and dispensing device Pentamix, PECD-01 and PECD Quick-01 are designed to be used in 3M ESPE's mixing, dosing and dispensing device, Garant™.

PECD-01 and PECD Quick-01 have the same fundamental scientific technology and the same intended use as Impregum Penta M Monosoft.

To provide evidence for safety biocompatibility testing was carried out. The results show that PECD-01 and PECD Quick-01 are safe devices.

The comparison for chemistry, performance data and indications for use shows that PECD-01 and PECD Quick-01 are substantially equivalent to the predicate devices.

In summary, it can be concluded that safety and effectiveness requirements for PECD-01 and PECD Quick-01 are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Desi W. Soegiarto
Regulatory Affairs Specialist
3M ESPE AG Dental Products
ESPE Platz
Seefeld, Bavaria,
GERMANY D-82229

MAR 2 6 2008

Re: K080514
Trade/Device Name: PECD-01, PECD Quick-01
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: February 18, 2008
Received: February 25, 2008

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080514

Indications for Use

510(k) Number (if known):

Device Name: PECD-01, PECD Quick-01

Indications For Use: Impressions for inlay, onlay, crown, and bridge restorations

Functional impressions

Fixation impressions

Implant impressions

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert B Betz DDS for Dr S Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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